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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,460	12/12/2003	Vilas M. Chopdekar	JFCT-1-03 (CIP)	9696

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EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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03/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,460	Applicant(s) CHOPDEKAR ET AL.	
	Examiner UMAMAHESWARI RAMACHANDRAN	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 9/19/2006. Claims 1-20 are pending and claims 11-20 have been withdrawn from consideration. Claims 1-10 are being examined on the merits herein.

Response to Remarks

Applicants' arguments regarding the rejection of claims 1-10 under 35 U.S.C. 112, second paragraph have been fully considered and found not persuasive. For example, compound cocaine is not an opioid. Cocaine is a tropane alkaloid, a stimulant and an anesthetic. Hence the rejection is maintained and given below for Applicants' convenience. Applicants' have not put forth any arguments towards the 102 and 103 rejections and have stated that they cannot respond to the rejections at this time (arguments dated 9/19/2006). Hence the following rejections are maintained and given below for Applicants' convenience. The office action is made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled

in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "opioid" in claim 2 is used by the claim to also mean "cocaine, pentazocine etc", while the accepted meaning is "a morphinan derivative having similar pain-relieving action as morphine." The term is indefinite because the specification does not clearly redefine the term. Claim 2 is limited to the opioid compositions wherein the opioid component is selected from a group consisting of various compounds, which are not opioid moieties. For example, such compounds as butorphanol, cocaine, dzocine, levorphanol, Inalbuphine, nalmeferene, pentazocine, pethidine, tilidine and tramadol are not considered to be opioids in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 894,609 ("GB '609").

GB '609 are directed to tannate forms of morphine alkaloids. GB '609 specifically prepares and claims morphine tannate, codeine tannate and dihydrocodeine tannate formulations in tablet form (see page 2, line 1-page 3, line 46). The formulations of GB '609 contains pharmaceutically effective amount of the opioid component within the

meaning of the instant claims. Thus, GB '609 anticipates all limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer US Patent 5,869,498 in view of GB '609.

Mayer teaches compositions comprising a first analgesic such as codeine, hydrocodone or oxycodone in combination with at least one secondary drug selected from the group of nonopioid analgesic, antitussive or antihistamine agents. (see abstract, col 1, lines 10-64; col 2, lines 30-45). Mayer exemplifies compositions containing suitable nonopioid analgesics to include acetaminophen, aspirin, caffeine; also antitussives such as dextromethorphan; and even antihistamines such as diphenhydramine or chlorpheniramine etc (see col 3, lines 50-44; see examples 3, 5, 8-12; col 8, lines 30-61). Mayer opioids components are bitartrate or phosphate salts. Mayer only fails to specifically employ opioid tannate salt as the opioid component in his formulations.

The teachings of GB '609 are discussed above. GB '609 specifically makes morphine tannate, codeine tannate and dihydrocodeine tannate formulations in tablet form for pharmaceutical use (see page 2, line 1-page 3, line 46). GB '609 further suggests that opioid tannate salts have much longer duration of action. (see page 1, line 30-50; page 2, line 125-page 3, line 10).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the morphine tannate salt of GB '609 in place of the opioid salts of Mayer, because as suggested by GB '609, the ordinary skill in the art would have had a reasonable expectation of success in prolonging the duration of action of

opioid component in the Mayer's formulations and therefore improving the duration of analgesia for patients in need of pain control.

Conclusion

No Claims are allowed.

The rejections from the previous office action are maintained. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617